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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,742	10/22/1999	KARL THEODOR KRAEMER	02481.1641	9957

22852 7590 07/01/2003

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WASHINGTON, DC 20005

EXAMINER
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WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/01/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/425,742

Applicant(s)

KRAEMER ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 and 28-38 is/are pending in the application.
- 4a) Of the above claim(s) 3,9 and 30-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10-23,29 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

Claims 1-23, 28-38 are pending. Claims 3, 9 and 30-38 are withdrawn from consideration, as they are directed to non-elected subject matter. The Amendment filed 6/2/03, Paper No. 25, amended claims 1, 22, 23, 28, and 29 and added claims 30-38.

#### ***Continued Prosecution Application***

The request filed on 11/1/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/425742 is acceptable and a CPA has been established. An action on the CPA follows.

In the previous Office Action, the Examiner erroneously stated that the request filed 11/1/02 was a Request for Continued Examination.

#### ***Election/Restrictions***

Newly submitted claims 30-38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: A method of treating skin substantially without hair cover is distinct from the originally prosecuted claims. The originally prosecuted claims are directed toward a method of use for treating acne or seborrhea, which are specific disorders that are associated with inflammation/infection of hair follicles. Thus, a method of treating any disorder comprising applying the composition to skin substantially without hair cover is a distinct invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Regarding the previous Election/Restriction requirement, Applicant argues, "It cannot be seen where claim 3 was restricted from the examined claims". The Examiner respectfully directs Applicant to page 4 of the Amendment filed 4/9/01, Paper No. 9, which elects a compound of formula I, wherein Y is a radical formula VI wherein R4 is 4-hydroxybutyl. Thus, instant claim 3 does not read on the presently elected compound of formula I.

Applicant's election with traverse of the Election of Species Requirement in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there is no burden on the Examiner to search the claims in their entirety. This is not found persuasive because Applicants independent claims are directed toward a composition which comprises four different variables, wherein each of those variables can comprise hundreds of compounds. Thus, it would be impossible to search every combination of these four ingredients. An undue burden is placed on the Examiner.

***112 Rejection Maintained***

The rejection of claim 10 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed 1/22/03, Paper No. 23, and those found below.

(i) Regarding claim 10, Applicant argues, "it might be said that 'acrylic acid ester copolymers' states a genus, and 'ethylene/acrylic acid ester copolymers' states a subgenus within that genus. This alleged 'double inclusion' is perfectly acceptable, so long as this does not render the claim indefinite or result in undue multiplicity". This argument is not persuasive. The Examiner respectfully points out that claim 10 recites acrylate copolymers, acrylate/acrylamide copolymers, and acrylate/octylacrylamide copolymers. The Examiner respectfully points out that this is a broad range together with a narrow range. It is respectfully pointed out that a broad range or limitation together with a narrow range or limitation that falls within the broad range or

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limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

### ***103 Rejection Maintained***

The rejection of claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29 under 35 U.S.C. 103(a) as being unpatentable over Cretois (5,558,859) in view of Dubois (6,162,444) is MAINTAINED for the reasons set forth in the Office Action mailed 1/22/03, Paper No. 23, and those found below.

The rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Cretois (5,558,859) in view of Dubois (6,162,444) as applied to claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29 above, and further in view of Lai (5,916,910) is MAINTAINED for the reasons set forth in the Office Action mailed 1/22/03, Paper No. 23, and those found below.

The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Cretois (5,558,859) in view of Dubois (6,162,444) as applied to claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29 above, and further in view of Ismail (5,541,220) is MAINTAINED for the reasons set forth in the Office Action mailed 1/22/03, Paper No. 23, and those found below.

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The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Cretois (5,558,859) in view of Dubois (6,162,444) as applied to claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29 above, and further in view of WO 92/21317 is MAINTAINED for the reasons set forth in the Office Action mailed 1/22/03, Paper No. 23, and those found below.

The rejection of claims 20-21 under 35 U.S.C. 103(a) as being unpatentable over Cretois (5,558,859) in view of Dubois (6,162,444) as applied to claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29 above, and further in view of WO 91/19701 is MAINTAINED for the reasons set forth in the Office Action mailed 1/22/03, Paper No. 23, and those found below.

Applicant argues, "the Examiner has alleged that the claim language 'wherein said compound of formula I is release from the film formed by application of said composition to the skin surface' is merely a property of the composition and its constituents, and so this language is given no weight. On the contrary, this claim language excludes those compositions that fail to release the compound, and so distinguishes the claimed subject matter". This argument is not persuasive. First, the Examiner respectfully points out that Applicant has misstated the Examiner's comment on page 5 of the previous Office Action. It is respectfully pointed out that the Examiner never stated that "this language is given no weight". The Examiner respectfully points out that since the combination of references teaches a composition comprises the same components, the composition of the combined references meets the limitation, "wherein said compound of formula I is released from the film formed". However, the Examiner respectfully points out that the intended use of the composition claims, i.e. the recitation of "application of said composition to a skin surface", is not given patentable weight. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference

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between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues, "Cretois teaches hair, eyelash, and nail compositions, and exemplifies hair styling mousses and mascaras. . . In contrast Dubois teaches skin compositions useful for treating cancers and skin affrications. . . One of ordinary skill in the art would not combine a hair treatment with a skin treatment without significant hindsight reasoning". This argument is not persuasive. The Examiner respectfully directs Applicant to Col. 6, lines 57-59 of Dubois which teaches that his compositions can be used in the treatment of hirsutism, androgenic alopecia, and hyperpilosity, which are all conditions related to hair growth. Since Dubois teaches his compositions for topical application, it is respectfully pointed out that Dubois does teach applying his compositions to the hair, as topical treatment of hirsutism, androgenic alopecia, and hyperpilosity results in application of the composition to the area that needs to be treated, wherein these areas have hair.

Applicant argues, "Cretois does not disclose a 'skin composition'". While this statement is correct, for the reasons in the above paragraph, there is motivation to combine Cretois with Dubois.

Applicant argues, "Cretois and Dubois teach compositions useful for different purposes, Cretois teaches hair and nail compositions and Dubois teaches skin compositions. Therefore, a skilled artisan would not find the motivation or reasonable expectation of success in the proposed

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combination of these two references. Nonetheless, the Examiner enlarged the subject areas of the two references until a common purpose could be stated: 'Dubois and Cretois are both directed to topical cosmetic compositions'. However, it is not enough even to find that alleged prior art compositions are directed to the same purpose". This argument is not persuasive. The Examiner respectfully points out that Applicant has only stated a small portion of the Examiner's motivational statement on page 4 of the previous Office Action. The Examiner respectfully points that the motivation statement on page 4 of the previous Office Action also states that Cretois teaches the addition of antiseborrheic agents to his composition and that the compound of formula (I), taught by Dubois, is taught as an antiseborrheic agent that is encapsulated in a liposome such that the concentration of the active agent in the sebaceous is higher and longer lasting in the epidermis and dermis, minimizing the passage of the active agent into the blood circulation. . .thus, one of skill in the art would be motivated to add the liposomes containing formula (I) of Dubois into the composition of Cretois because of the expectation of achieving an anti-seborrheic composition that is more effective and longer lasting, and which does not result in adverse side-effects as a result of seeping into the circulatory system.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period



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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
June 25, 2003



SREENI PADMANABHAN  
PRIMARY EXAMINER

6/27/03